## **EXHIBIT B**



## United States Attorney Northern District of California

150 Almaden Boulevard, Suite 900 San Jose, California 95113 (408) 535-5061 FAX:(408) 535-5066

May 9, 2019

## VIA FEDERAL EXPRESS

Karen W. Dyer MT(ASCP), DLM Director, Division of Clinical Laboratory Improvement and Quality Centers for Medicare & Medicaid Services 7500 Security Blvd. Baltimore, Maryland 21244

Re: Document Access Request -

United States v. Elizabeth Holmes and Ramesh Balwani, 18-CR-00258 EJD

Dr. Ms. Dyer:

Federal criminal charges have been filed against Elizabeth Holmes and Ramesh Balwani, and that prosecution is currently pending under case number 18-CR-00258 EJD in the Northern District of California.

In connection with this prosecution, Defendants have requested certain categories of documents that may have been created or compiled by the U.S. Centers for Medicare & Medicaid Services. The United States Attorney's Office already has produced to Defendants documents previously obtained from CMS, but recognizes that there may be additional materials responsive to Defendants' requests in the possession of CMS to which my office does not have access.

Accordingly, the United States Attorney's Office hereby requests access to the following documents and information in connection with the above-referenced case, to the extent such documents are within CMS's possession:

1. Any and all correspondence or communications regarding Theranos between the federal government and John Carreyrou, The Wall Street Journal, or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;

- 2. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding Theranos' Clinical Laboratory Improvement Amendments ("CLIA") compliance during the time period of the charged conspiracies, including but not limited to those that concern the 2015 CLIA survey of Theranos;
- 3. Any and all correspondence or communications regarding Theranos between the government and any clinical laboratory company or association affiliated with clinical laboratories (including but not limited to LabCorp, Quest Diagnostics, and the American Clinical Lab Association), or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;
- 4. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the FDA's determination of the type of FDA approval required for Theranos' proprietary technology;
- 5. Any and all FBI 302s or other agency ROIs memorializing government communications with witnesses, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same; and
- 6. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the 2013 CLIA survey of Theranos.

Please write back at your earliest convenience to convey CMS's response to the above requests. Feel free to contact me by telephone at any time should you have any questions regarding this matter.

Very truly yours,

ADAM A. REEVES Attorney for the United States Acting Under Authority Conferred by 28 U.S.C. § 515

JOHN C. BOSTIC Assistant United States Attorney

CC (via email): Lindsay Turner, HHS/OGC